Applicant's election without traverse of the species CMV promoter in the reply filed on 8 January 2008 is acknowledged.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallatin et al. (A, newly cited).

Claim 1 is drawn to a method for determining whether a gene product has an activity of interest comprising: (a) co-transfecting a cell with (i) a first vector comprising a gene coding for a test protein and (ii) a second vector comprising a gene coding for a reporter protein; (b) expressing said test protein and said reporter protein in a transfected cell; (c) measuring abundance and/or activity of said reporter protein, wherein said abundance and/or activity of said reporter protein is modulated by the presence of a protein having said activity of interest; and (d) determining whether said test protein has said activity of interest. Claim 2 specifies within claim 1 that said first vector and/or said second vector further comprise promoter sequences. Claim 3 specifies within claim 1 that co-transfecting comprises contacting said cell with said first vector, said second vector, and a transfection reagent. Claim 7 specifies within claim 1 that abundance of said reporter protein is measured. Claim 20 specifies within claim 1 that said first vector is selected from a library of vectors, at least two members of said library comprising genes for different proteins, and said library is screened for one or more members encoding proteins

having the activity of interest. Claim 21 specifies within claim 20 that said library comprises at least 1000 different genes, and 22 specifies use of a multi-well plate.

Gallatin et al. teaches, e.g., at column 5, second full paragraph, in a cell, a first construct comprising a reporter gene driven by a promoter, and a second DNA sequence from a library, wherein expression of the reporter gene is detected.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 8-19, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. (A) in view of Hillman et al. (B).

Claims 1 and 3 are included in the instant rejection as they encompass the embodiments of claims 4-6, 8-19, 23 and 24, which depend therefrom. Claim 4 specifies within claim 3 that said transfection reagent is at least one proprietary lipid composition selected from the group

consisting of DMIRE-C, cellFECTIN®, lipofectin®, oligofectAMINE TM, lipofectAMINE TM, lipofectAMINE PLUS TM, lipofectAMINE 2000 TM, fugene, Effectene, TransFast TM, Tfx TM, Transfectam®, siPORT TM amine, siPORT TM lipid, and GeneJuice. Claim 5 specifies within claim 4 that said transfection reagent is fugene. Claim 6 specifies within claim 3 that co-transfecting comprises: (i) coating a well of a multi-well plate with a polycation polymer; (ii) contacting said cell with said first vector, said second vector, and said transfection reagent in said well; and (iii) incorporating said first and said second vectors in said cell to produce said transfected cell. Claim 8 specifies within claim 7 that said reporter protein is measured by luminescence. Claim 9 specifies within claim 7 that said reporter protein is measured by a binding assay for said reporter protein. Claim 10 specifies within claim 7 that said reporter protein is measured by electrophoretic analysis. Claim 11 specifies within claim 1 that said activity of said reporter protein is an enzymatic activity that catalyzes the reaction of a substrate to form a product, and said enzymatic activity is measured by adding said substrate and measuring consumption of said substrate and/or formation of said product. Claim 12 specifies within claim 11 that said enzyme activity is selected from the group consisting of beta-galactosidase activity, beta-1actamase activity, and luciferase activity. Claim 13 specifies within claim 1 that said reporter protein affects or regulates a biological process in said cell and wherein said reporter protein is measured by observing an indicator of said biological process. Claim 14 specifies within claim 13 that said indicator is selected from the group consisting of change is cell morphology, change in abundance of a native protein, change in post-translational modification of a native protein, change in transcription of a native gene, and change in secretion of a native protein. Claim 15 specifies within claim 1 that said activity of said reporter protein is

aggregation and said reporter protein is Sup35. Claim 16 specifies within claim 1 that said activity of interest is pro- apoptotic or anti-apoptotic activity. Claim 17 specifies within claim 1 that confirming that expression of said test protein results in a change in an indicator of apoptosis by another assay. Claim 18 specifies within claim 17 that said indicator of apoptosis is selected from the group consisting of DNA fragmentation, caspase activation, annexin staining on the outer membrane, DNA ladder formation, and production of cleavage products of caspase such as DFF45, alpha fodrin, or lamin A. Claim 19 specifies within claim 1 further comprising: repeating said method with another cell having a different genetic background. Claim 23 specifies within claim 1 further comprising: (d) repeating said method using a third vector instead of said first vector, said third vector differing from said first vector in that it i) does not code for a protein; ii) codes for a protein that is known to not have the activity of interest or iii) does not have a promoter sequence; and (e) comparing the activity and/or abundance of the reporter protein measured with said first vector and said third vector to determine whether said test protein has said activity of interest. Claim 24 specifies within claim 1 that repeating said method without said first vector; and comparing the activity and/or abundance of the reporter protein measured with and without said first vector to determine whether said test protein has said activity of interest.

Gallatin et al. (A) is described above. Gallatin et al differs from the claimed invention in not teaching specifically the recited transfection reagents, the use of luminescent, e.g., luciferase, or specifically-binding reporter gene products, or an apoptosis-related reporter gene, e.g., annexin, or repetition of the process to perform a negative control.

Hillman et al. teaches, e.g., at column 16, first full paragraph, the use of luciferase as a reporeter gene. Also taught, e.g., at the paragraph bridging columns 16 and 17, is the detection of a protein produced from a gene of interest using an immunoassay or a competitive binding assay. At column 22, fourth full paragraph, Hillman et al. teaches that polycationic amino polymers may be used to transfect cells. At the paragraph bridging columns 36 and 37, Hillman et al. teaches the evaluation of the apoptotic state of transfected cells to identify them.

It would have been obvious to one of skill in the art to have practiced the screening method of Gallatin et al. employing any of the various selection methods set forth above, as taught by Hillman et al. The use of a known reporter gene as a reporter in any desired construct would have been expected by one of skill in the art to have operated correctly. With respect to the use of negative controls, such are and were widely used in the prior art as a basic tool of scientific measurement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite products by names which are trademarks. However, these products represent structure which determines the metes and bounds of the claimed invention. As such, the claims do not have clear metes and bounds, and as such are indefinite. See MPEP §2173.05(u).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
18 April 2008

/James S. Ketter/
Primary Examiner, Art Unit 1636